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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/578,706 | 05/10/2006 | Vitali Tararov | LNK-014 | 3660 |

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| SMITH PATENT CONSULTING CONSULTING, LLC | | |
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| ALEXANDRIA, VA 22314 | | |

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| EXAMINER | |
| DENTZ, BERNARD I | |

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| ART UNIT | PAPER NUMBER |
| 1625 | |

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| MAIL DATE | DELIVERY MODE |
| 01/18/2008 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | | |
|------------------------------|------------------------|--|---------------------|--|
| Office Action Summary | Application No. | | Applicant(s) | |
| | 10/578,706 | | TARAROV ET AL. | |
| | Examiner | | Art Unit | |
| | Bernard Dentz | | 1625 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12-26-2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-10, 12 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims withdrawn from consideration are 5 and 11,13 and 14 and non-elected parts of claims 4,6-10 and 12.

The restriction is proper because the US Patent 5,286,883 discloses that the product of the reduction is commonly converted into the corresponding lactone. See col. 1, lines 14-32. It is made final. Non-elected claims 5, 11, 13 and 14 are withdrawn from consideration.

Claims 1-3 and 15 in whole and claims 4, 6-10 and 12 in part, are deemed to read on the elected process. Applicants have elected a multi-step process for making atorvastatin in which a key intermediate is compound (I) in which R is $\text{CH}_2\text{CH}_2\text{NH}_2$ recited in part (e) of claim 4.

This compound is made by reducing the corresponding $\text{CH}_2\text{CH}_2\text{CN}$ (the cyanoethyl) compound.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-4, 6-10, 12 and 15 are rejected under 35 USC 101 since the disclosed invention is inoperative and therefore lacks utility. The multi-step synthesis is based on steps which have been disclosed as inoperative in a journal article of which all 3 of the instant inventors are authors.

The process of part (e) of claim 4 requires the conversion of a compound of formula (I) where R is CH_2R^2 where R^2 is tosylate into the compound where R^2 is cyano. See p. 12, lines 14-16 and p. 25, line 10.

However Tararov et al. Eur. J. Org. Chem, P. 5543-5550 (2006) discloses that preferred compounds of instant formula (I) (see p. 8 of the specification) in which instant

S¹ is tert-butyldiphenylsilyl or tert-butyldimethylsilyl and R² is tosylate or iodo could not be converted to the corresponding cyano compound

See p.5545, col. 2, second complete par. in which the first sentence is:

"Unfortunately, it was not possible to achieve substitution of the tosyl group by cyanide under a variety of conditions." See the rest of the par. where a wide variety of conditions are described.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4,6-10, 12 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Of course claims 1-3, 6-10 and 15 are incomplete in not (especially independent claim 1) in not reciting the elected process for making atorvastatin given in claim 4 part (e). Applicants must draw claim 1 to the elected method for making atorvastatin.

Applicants must cancel all of the non-elected material from the claims

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bernard Dentz whose telephone number is 571-272-0683. The examiner can normally be reached on Mon.-Fri from 8 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on 571 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Dentz

1-11-2008

A handwritten signature in black ink, appearing to read "B Dentz", with a stylized flourish at the end.

BERNARD DENTZ
PRIMARY EXAMINER